IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.*, and STATE OF NEW YORK *ex rel.*,	*	
MICHAEL I. LEVINE, M.D.,	*	
Plaintiff-Relator,	*	
		Civil Action No. 12 Civ. 5103 (LGS)
v.	*	
ROBERT MATALON, MD, JOSEPH SHAMS, MD, DANIEL MATALON, MD, ALBERT MATALON, M.D,	*	
VASCULAR ACCESS CENTERS (and each of its subsidiary and/or related Corporations)	*	
2929 Arch Street Suite 620 Philadelphia, PA 19104	*	
Serve on:	*	
JAMES McGUCKIN, MD, (and any and all clinics owned, run, managed or operated by him)	*	
2929 Arch Street Suite 620 Philadelphia, PA 19104	*	
Philadelphia Vascular Institute, 585 County Line Road Radnor PA 19085	*	
Defendants.	*	
	*	

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RELATOR'S AMENDED COMPLAINT AND JURY DEMAND

Plaintiff-Relator, Dr. Michael I. Levine, MD (Dr. Levine), by and through his undersigned counsel, brings this *qui tam* action in the name of the United States of America, and the State of New York, against the above named Defendants (hereinafter collectively referred to as "Defendants").

1. This is an action to recover damages and civil penalties arising from false claims and services provided to patients requiring renal replacement therapies, specifically hemodialysis, that are reimbursed by Medicare, Medicaid, and other Federal Programs including the federally-funded End Stage Renal Disease ("ESRD") program.

2. As outlined in more detail below, Defendants' illegal activities center on the unnecessary provision of "vascular access services" and percutaneous interventions upon ESRD patients and their arteriovenous vascular accesses (and the associated draining veins and feeding arteries), including but not limited to duplex ultrasound, percutaneous balloon angioplasty ("angioplasty"), stent deployment, and angiography in patients requiring hemodialysis.

3. The Court on October 19, 2018 [ECF 28] by Order approved settlement with the VAC Defendants and stay of claims involving the Non-VAC Defendants (both as defined in the Court's Order). This Amended Complaint does not affect and is not intended to affect in any way the requirements of this Court's Order or related settlement.

OVERVIEW OF THE FRAUDULENT SCHEME

4. For ease of understanding, Dr. Levine provides the following general description of the fraudulent scheme with details to be stated later below: As part of the hemodialysis – also known as dialysis – treatment, the patient's arteriovenous hemodialysis vascular access system comprised of the access itself (either an arteriovenous fistula or prosthetic graft), and the veins draining and the arteries feeding the access are monitored by the dialysis provider (usually a nurse or technician employed by the dialysis unit) and/or the patient's primary or treating nephrologist using various techniques described in more detail below. When this monitoring indicate the presence of clinically significant obstruction in the patient's vascular access system that is either preventing the dialysis treatment from effectively removing toxins from the blood, placing the access at increased risk of thrombosis, or causing a complication in what should otherwise be an uneventful hemodialysis treatment, the treating nephrologist will refer the patient to a vascular access specialist (who often, but not always, see patients at for-profit, free-standing "vascular access centers") to perform a one-time diagnostic procedure called a fistulagram (real time radiographic imaging of the access system by virtue of the infusion of x-ray contrast fluid),[1] and if medically appropriate, to then repair the patient's vascular access using percutaneous/endovascular techniques such as balloon angioplasty to a condition sufficient to allow dialysis to be effective per accepted standards, minimize the risk of

[1] A fistulagram is a form of medical imaging which involves penetrating the skin and blood vessel with a needle, and inserting a catheter into the blood vessel (usually the arteriovenous fistula or graft), the injection of dye into the punctured vessel via the catheter, and the X-ray imaging of the vessel.

thrombosis, and enable the patient to have future dialysis treatments free of untoward events as much as can otherwise be reasonably expected.

5. As Dr. Levine knows from personal observation, however, once a patient was referred to Dr. James McGuckin and the access centers he owned and controlled, or to Dr. Shams and Beth Israel Medical Center's vascular access center, for what was supposed to be a one-time fistulagram and other possible associated procedures that were medially indicated, Dr. McGuckin and Dr. Shams (in the case of the latter with the assistance and knowing collaboration of Drs. Matalon) would engage in a practice called "self-referral," that is, they would schedule and perform, respectively, numerous unnecessary further access center visits, fistulagrams, "angioplasties,"[2] and other endovascular interventions such as stent deployment, over the course of ensuing months or years, while ignoring the actual medical needs of the patient, without the input or referral of the primary nephrologist, and irrespective of whether or not the access system showed evidence suggestive of clinically significant obstruction. Dr. McGuckin and Dr. Shams thereby in effect treated these patients as a means of obtaining additional, fraudulent Medicare and Medicaid revenue from the Government.

6. The violations of the False Claims Act arose because Defendants (as described more fully below) have submitted, and/or caused to be submitted, false and

[2] An angioplasty is a procedure for clearing a vascular blockage or narrowing (stenosis) by inserting a catheter with a balloon attached into the patient's blood stream so as to physically expand the width of the narrowed vessel. Sometimes a stent is inserted as well into the arteriovenous vascular access system to treat a narrowing which did not adequately respond to the angioplasty alone or to prevent rapid re-narrowing of an angioplastied vessel segment.

fraudulent claims, and/or false statements material to false and fraudulent claims, and in payment thereof received funds from Medicare and Medicaid, which claims and statements the Defendants knew to be false and fraudulent, or as to which they acted in reckless disregard of the claims' and statements' false and fraudulent nature, or as to which they acted in deliberate ignorance of the claims' and statements' false and fraudulent nature.

7. Plaintiff-Relator is the "original source" of the information contained in this Amended Complaint within the meaning of 31 U.S.C. § 3730(e) (4) and has personal knowledge of the fraudulent scheme, described in detail below, pursuant to which the Defendants presented false claims, and false statements material to false claims, to the United States.

JURISDICTION AND VENUE

8. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732 because this action arises under the laws of the United States. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a).

9. Venue is proper in this District because Defendants resided, transacted business, and can be found in this judicial district.

PARTIES AND OTHER RELEVANT PERSONS

Plaintiff-Relator Dr. Michael Levine

10. Dr. Levine is an Internal Medicine physician who is board certified in Internal Medicine and Nephrology. He is trained in the diagnosis and management of kidney disease and/or kidney disorders. He also has extensive training and experience

in managing ESRD patients, supervising hemodialysis and associated therapies, and the surveillance, assessment, and percutaneous treatment of arteriovenous hemodialysis vascular access. Dr. Levine is also trained as an interventional nephrologist, meaning that he has often performed the very procedures at issue in this matter, and, therefore, has first-hand, direct knowledge of the legal requirements and limits imposed by the Centers for Medicare and Medicaid Services (CMS) in billing the Government for such procedures.

11. Dr. Levine also has trained other nephrologists to perform the same procedures at issue in this case. The nephrologists he has trained have gone on to have productive clinical and academic careers in the field of hemodialysis vascular access treatment and research.

12. Dr. Levine was a contributing author of the National Kidney Foundation's first Dialysis Outcomes Quality Initiative (NKF-DOQI) for Vascular Access. Over the 22 years since it was first issued in 1997, NKF-DOQI has become the "gold standard" for vascular access therapy in the United States.

13. Dr. Levine is also an advocate in the United States for the use of arteriovenous fistulas ("AVF" or "fistulas") as the preferred means of accessing an ESRD patient's circulation to perform hemodialysis treatments (to be explained further below). As one of the authors of the K-DOQI Vascular Access Guidelines he has played a key part in promoting fistulas for treatment and management of ESRD patients, and in promoting routine access surveillance in dialysis units to prevent critical access malfunction and access thrombosis.

14. Following his education and training as an interventional nephrologist, from approximately 1997 to 2011, Dr. Levine practiced nephrology and interventional nephrology in the Milwaukee, Wisconsin area. Dr. Levine observed that he and other Milwaukee-area nephrologists and interventionalists with whom he worked complied with the regulations and limitations, discussed further below, governing billing and receiving payment from the Medicare and Medicaid programs.

Dr. James McGuckin, MD, and his VACs and PAC, and Defendants Dr. Robert Matalon, MD, and his Sons, Drs. Albert and Daniel Matalon, MD

15. Beginning in 2009, for personal reasons, Dr. Levine relocated from Wisconsin to the New York-New Jersey region, where he was born and raised. There he was associated with various hospitals, hemodialysis treatment facilities, and vascular access centers in the New York and New Jersey regions operated and/or managed by either Dr. James McGuckin, MD, or by Defendants Dr. Robert Matalon, MD (Dr. Robert Matalon or simply "Dr. Matalon"), and his sons, Dr. Albert Matalon, MD, and Dr. Daniel Matalon, MD.

16. In addition, from the end of March, 2009 through July, 2009, Dr. Levine was employed by Vascular Access Centers ("VAC") and Philadelphia Access Centers ("PAC") owned by Defendant Dr. James McGuckin, Jr. (Dr. McGuckin). He actively worked from the end of March, 2009 through April, 2009 at VAC/PAC.

17. VAC is a Pennsylvania limited liability partnership maintaining its principal place of business at Cira Centre, 2929 Arch Street, Suite 620, Philadelphia, Pennsylvania 19104. VAC provides comprehensive dialysis access maintenance by and through various vascular access centers located throughout the United States.

18. Dr. McGuckin is the owner, founder, and principal of VAC.

19. McGuckin, through VAC and other corporations, has established a web of at least twenty-three subsidiary corporations that provide vascular access services throughout the United States.

20. McGuckin, through VAC, creates these corporations by entering into partnerships with doctors in various locations in the United States to develop and manage medical practices specializing in vascular care. Under the terms of the partnership, which are usually formalized through an operating agreement, McGuckin or VAC is the manager and majority member of the partnership.

21. The corporations created by McGuckin and/or VAC include: American Access Care of PA, LLC, American Access Care of South Philadelphia, PA, LLC, Philadelphia Access Institute Centers, Peripheral Vascular Institute of Philadelphia, Vascular Access Center of Pittsburgh, Vascular Access Center of Atlantic County, Texas, Vascular Access Center of West Orange (New Jersey), Vascular Access Center of Trenton (New Jersey). Vascular Access Center of Prince Georges County & Washington, D.C., Vascular Access Center of Durham, N.C., Vascular Access Center of Georgia, Vascular Access Center of Atlanta, Vascular Access Center of South Atlanta, Vascular Access Center of Jacksonville, Florida, Vascular Access Center of Memphis, TN, Vascular Access Center of Mississippi, Vascular Access Center of New Orleans, Vascular Access Center of Southwest, Louisiana, Vascular Access Centers of North Shore (Louisiana), Vascular Access Center of Houston, Vascular Access Center of South Los Angeles, and the Vascular Access Centers of Seattle, Washington.

Dr. McGuckin, along with all of the foregoing entities named in paragraphs 18-20 are referred to below as the "VAC Defendants."

22. Dr. Robert Matalon, MD is a Nephrologist and an Associate Professor of Clinical Medicine at New York University Langone Medical Center specializing in Internal Medicine and Nephrology in the New York, New York metropolitan area. Dr. Matalon is also affiliated with a number of hospitals including the NYU Hospital for Joint Diseases, NYU Hospitals Center, Bellevue Hospital Center, Beth Israel Medical Center, Petrie Division, New York Downtown Hospital, Rusk Institute of Rehabilitational Medicine, Tisch Hospital, Beth Israel Medical Center, Herbert & Neil Singer Division, and IMC St. Johns, Episcopal Hospital in Brooklyn, NY. He is a member of Nephrology Associates of Manhattan, and also owns and operates Lower Manhattan Dialysis Centers at 17th and 34th streets, Chinatown Dialysis Center, and River Renal Dialysis Center located at Bellevue Hospital, which is part of the New York City Health and Hospitals Corporation. All of these facilities are located in Manhattan, New York City, N.Y. Since the filing of the original complaint herein, Beth Israel Medical Center was purchased by Mount Sinai Health Care System.

23. Albert Matalon, M.D. is the son of Robert Matalon, M.D. and is a member of Nephrology Associates of Manhattan and helps to staff his father's dialysis units, and provide medical care for the patients of their practice. He is an internist and nephrologist.

24. Daniel Matalon, M.D. is the son of Robert Matalon, M.D. and is a member of Nephrology Associates of Manhattan and helps to staff his father's dialysis units,

and provide medical care for the patients of their practice. He is an internist and nephrologist.

Dr. Joseph Shams, MD and Beth Israel Medical Center's Vascular Access Center

25. Joseph Shams, MD, is board certified in Interventional Radiology with privileges at Beth Israel Medical Center in New York, NY and Beth Israel Medical Center, Kings Highway Division in Brooklyn, NY. He also performs vascular and diagnostic radiology with practices in Jersey City, New Jersey; Brooklyn, New York; and New York, New York. Dr. Shams also actively works at Union Square Interventional Radiology Center.

26. Beth Israel Medical Centers is an acute care hospital in New York, and at the time of the original filing was a member of Continuum Health Partners, and is currently owned by Mount Sinai Health Care System.

ADDITIONAL FACTUAL BACKGROUND

Government Reimbursement for ESRD Services

27. Medicaid is a health insurance program established for the poor by Title XIX of the Social Security Act and is administered by the States, 42 U.S.C. § 1396 *et seq.* Defendants received payments from Medicaid.

28. The United States Government provides reimbursement to the States for a percentage of the health care expenses paid under the Medicaid program.

29. Defendants also received payment from the Medicare program. Medicare was established by Title 18 of the Social Security Act, 42 U.S.C. § 1395 *et seq.* and covers medical expenses for elderly and disabled individuals. A component of the

Medicare program is the Medicare End Stage Renal Disease Program (hereinafter "Medicare ESRD"), which provides federal reimbursement for patients with ESRD.

30. Many of Defendants' patients are elderly, disabled, and/or financially challenged individuals with ESRD. The cost of their medical care was, and is, reimbursed by the Medicare and Medicaid programs.

End Stage Renal Disease

31. Chronic kidney disease which has progressed to "end stage" manifests as the complete or almost complete failure of the kidneys to function and thereby remove waste products from the body and regulate the body's chemical, electrolyte, and fluid balance. ESRD occurs when the kidneys can no longer function at a level necessary for daily life and usually results when chronic kidney disease has progressed to a point where a patient's kidney function is less than ten percent of normal kidney function. Failure of a person with ESRD to receive renal replacement therapy in the form of either kidney transplantation, peritoneal dialysis, or hemodialysis, ultimately results in death.

32. Recognizing the efficacy of renal replacement therapy, in 1972, Congress enacted the ESRD program to provide Federal reimbursement for ESRD treatments.

33. Most ESRD patients cannot immediately, and many ultimately will never receive a kidney transplant. As a result, hemodialysis is a mandatory treatment protocol in order for ESRD patients to remain alive, in addition to the much less frequently utilized alternative known as chronic ambulatory peritoneal dialysis (CAPD).

34. Hemodialysis utilizes a machine that safely removes and pumps blood within a closed system consisting of a circuit of tubing through an artificial kidney/dialysis membrane that removes toxic impurities and wastes from patients' bodies via their blood streams, and returns the “cleansed” blood to the patient.

35. Most patients undergo hemodialysis treatments three times per week in a medical facility commonly referred to as a "dialysis facility" or “dialysis unit.”

36. It is expected and required by Medicare and Medicaid that dialysis facility staff, and the patients’ primary nephrologists, are responsible for providing safe dialysis treatments, and for the monthly assessment and management of a number of key areas vital and unique to the ESRD patient. These areas include: adequacy of dialysis, anemia management, nutrition, bone metabolism, potassium homeostasis, iron levels, blood pressure control, extracellular volume status, and “vascular access surveillance.”

37. In return for these services, including surveillance of the patients’ “vascular accesses,” the nephrologist is reimbursed by the federal government a monthly capitated fee which is proportional to the number of patient visits up to a total of four per month, defined as direct patient-doctor contact.

38. Hemodialysis patient-doctor interactions and assessments are to be documented in the patient’s medical record, or “chart,” and each month, at a minimum there must be a “progress note” written by the nephrologist indicating that the key areas of hemodialysis patient management have been reviewed and abnormalities addressed. This note is also known as the “monthly comprehensive note.”

39. In addition, the Government's ESRD reimbursement rules require that the nephrologist and the dialysis facility coordinate an interdisciplinary care plan that reviews the key areas of patient management along with psycho-social parameters and plans to address those areas that are out of compliance with expected clinical outcomes. Dieticians, social workers, nurses, and nephrologists all contribute to and sign off on the care plan based on the areas of patient care that fall within their jurisdiction.

The Importance of "Access" to an ESRD Patient's Circulatory System

40. In order to perform chronic outpatient hemodialysis there must be the ability to safely and repeatedly obtain access to patients' circulation. Accordingly, patients with ESRD require what is known as "long term" or "permanent" "vascular access."

41. There are currently four primary methods of gaining vascular access for hemodialysis: arteriovenous fistulas and grafts, and tunneled and non-tunneled catheters ("catheters").

42. The two preferred methods of gaining access are through either grafts or fistulas, compared to catheters, with fistulas considered the "state of the art" or "preferred" treatment by most practitioners, compared to grafts.

43. Regardless of the method used, ESRD patients can, and do, suffer from complications related to their access sites. These include infections and, in the case of fistulas and grafts, the formation of narrowings or stenoses within the fistula or graft vessel itself and/or the vein(s) draining and the artery(s) feeding the access . The "vascular access surveillance" performed by the nephrologist, and by a dialysis facility

under the nephrologist's oversight, is intended to detect the clinical manifestations of these complications thereby allowing the complications to be diagnosed and treated early and pre-emptively. Consistent with accepted and expected medical practice, the presence or absence of these clinical manifestations are to be documented on a regular basis, as well as when manifestations indicative of stenosis formation acutely appear, in the patients' medical records.

44. If left untreated, narrowings within a patient's vascular access system will often progress, ultimately leading to critical access failure (inability to provide the scheduled prescribed dialysis treatment) and/or significant clinical complications such as arm swelling or prolonged bleeding following dialysis needle removal. Additional invasive procedures are then required to salvage the access and restore it to its prior level of acceptable function thereby enabling it to support the prescribed dialysis treatments. At times it is necessary to create a new access site if it's determined the failed or malfunctioning access must be abandoned.

45. The Government's reimbursement rules incorporate the national standard of care principles first promulgated in 1997 by the National Kidney Foundation. These principals are outlined in a series of publications that are known as the "Dialysis Outcomes Quality Initiative in the United States" and are commonly referred to as the "DOQI Guidelines." Plaintiff-relator participated in the development of the DOQI Guidelines.

46. Under the DOQI Guidelines, treatment of a patient's access is expected to be "proactive" rather than "reactive." Thus, rather than waiting until a patient presents with critical access failure or dysfunction necessitating urgent intervention so the

patient may receive dialysis before the potentially life threatening sequlae of ESRD have time to develop, the Government reimburses the patient's primary nephrologist and the patient's dialysis facility to monitor a patient's access site for signs of dysfunction while the access is still usable for dialysis. In addition, the "care plan" created for each patient requires analysis and recommendations for maintaining the functionality of the patient's vascular access.

Medicare and Medicaid Requirements for Claims and Payments for Dialysis-Related Treatments

47. Medical necessity is a fundamental requirement for Medicare coverage. Medicare does not cover any expenses incurred for services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." 42 U.S.C. § 1395y(a)(1)(A).

48. Every health care provider seeking reimbursement under Medicare is obligated to assure that services it provides, "(1) will be provided economically and only when, and to the extent, medically necessary; (2) will be of a quality which meets professionally recognized standards of health care; and (3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities." 42 U.S.C. § 1320c-5(a).

49. "All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's

specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary." 42 C.F.R. § 410.32.

50. Medicare and Medicaid pay for the patient's primary, or treating, nephrologist's surveillance of the patient's access as part of a monthly capitated reimbursement to the nephrologist.

51. The nephrologist submits claims to the Medicare and/or Medicaid program to obtain these capitated payments by submitting, usually electronically, a claim form called a CMS Form 1450 (UB-04) (Form 1450). Hospitals and other facilities use a CMS Form 1500 (Form 1500) to make claims for payment.

52. Providers who provide medical services to patients use a system of codes to describe their diagnosis and treatment of a patient. The codes are used by the provider to claim reimbursement from Government and private insurance programs, among other purposes. The standard treatment coding system in the United States was developed by the American Medical Association, and is called "Current Procedural Terminology," or "CPT," codes. Another coding system is the Healthcare Common Procedure Coding System (HCPCS). HCPCS codes are required to be used when billing Medicare and Medicaid. Generally, the HCPCS codes are identical to the CPT codes.

53. In order to claim reimbursement from the Government, providers include one or more HCPCS codes for the procedures they performed on a given patient. Medicare and Medicaid, specifically, base the reimbursement amounts they pay to providers on these codes.

54. The capitation payment to nephrologists depends on how many times per month the nephrologist sees the patient up to four times per month. During times relevant to this complaint, nephrologists utilized HCPCS code 90960 to report that they conducted 4 or more patient visits per month; they used HCPCS code 90961 to report they provided 2-3 visits per month; and HCPCS code 90961 was used to claim 1 patient visit per month by the physician. Generally, the payment by Medicare or Medicaid increased with an increasing number of visits per month.

55. Because a patient's dialysis facility and treating nephrologist are paid by Medicare and Medicaid to monitor each patient's hemodialysis vascular access, other medical professionals should not take that responsibility upon themselves. Doing so would not only be duplicative, it would encourage nephrologists and dialysis facilities to reduce the treatment they provide to patients even though they are expected to perform the service and are paid for doing so under the Medicare and Medicaid programs.

56. Furthermore, because the nephrologist and the dialysis facility are in the best position to determine if there is evidence to suggest additional evaluation of and interventions upon the patient's access are medically reasonable and necessary in order to maintain optimal, complication free access function, the dialysis facility and the nephrologist, not third-party treating physicians or access centers, are the individuals whom Medicare and Medicaid expect to make the decision to refer patients to specialists for additional evaluations and interventions such as diagnostic angiograms, angioplasty, and, when necessary, surgical revision, prior to the onset of critical access dysfunction, thrombosis, or other associated complications.

57. Referrals for further evaluations and interventions, moreover, must be based on well-defined and established clinical indicators of access malfunction. These include such things as excessive bleeding from an access because a stenosis is causing intra-access hypertension, suboptimal dialysis performance, elevated "venous pressure" within the dialysis circuit, and/or diminished intra-access blood flow as measured by specialized technology employed during the time of the dialysis treatment.

58. In summary, in order to bill Medicare for a particular item or service, such as a fistulagram, an access center was required to follow the Medicare Local Coverage Determinations (LCDs) for that item or service applicable to the region in which the access center operated. LCDs set forth the requirements for when a particular item or service is covered, and thus reimbursable, by Medicare.

59. For a provider to seek reimbursement for performing a fistulagram or related services on an ESRD patient, the applicable LCDs required that the patient have previously undergone a clinical examination during and by virtue of data obtained from the hemodialysis treatment itself that produced diagnostically specific and appropriate clinical findings demonstrating a need for further evaluation (a fistulagram) and therapies as indicated to reestablish physiologically appropriate flow in the dialysis fistula, and that such findings be documented in the patients' medical records.

60. In the absence of such clinical findings suggesting the need for further evaluation and to re-establish appropriate flow in a dialysis fistula, the pertinent LCDs provided that Medicare would not reimburse for fistulagrams or related procedures.

61. The applicable LCDs also provided that Medicare would not pay for services, including fistulagrams, that were only screening in nature.

62. With respect to angioplasties, the LCDs generally provided that these procedures will be considered reasonable and necessary when the documentation supports the presence of residual, hemodynamically significant stenosis, of greater than or equal to 50 percent of the vessel diameter, and further that angioplasty of vessels not documented to be stenosed significantly (defined as greater than or equal to 50 percent) by angiography or ultrasound will be considered not medically necessary.

63. The definition of "hemodynamically significant" is the stenosis is causing one or more of the following clinical manifestations detected during, immediately before, or immediately after the dialysis treatment: Increased dialysis circuit venous pressure, decreased dialysis circuit arterial pressure, difficult access cannulation, inability to achieve the prescribed blood pump flow rate, arm swelling, prolonged bleeding bleeding from needle sites, inadequate urea clearance, recirculation, and decreased or decreasing intra-access blood flow. Furthermore, it is expected treatment of the stenosis will result in resolution or improvement in the hemodynamic/clinical perturbation which should be subsequently documented in the patient record.

THE FALSE CLAIMS ACT SCHEME

Procedural History of this Action

64. Dr. Levine initially filed this action on June 29, 2012. On July 9, 2018, the Department of Justice (DOJ) filed a Notice of Election to Intervene as against only the VAC Defendants, and on October 9, 2018, filed a corrected Notice to Intervene against only the VAC Defendants.

65. On October 19, 2018, the parties filed ECF 28, a Stipulation and Order of Settlement and Dismissal settling the claims in the original action against the VAC Defendants, and setting out certain conditions under which the claims against the VAC Defendants would be dismissed.

66. Inasmuch as those terms have not yet been fully satisfied by the VAC Defendants, they remain as defendants in this action. This Amended Complaint sets forth Dr. Levine's amended and supplemental allegations as the Matalon Defendants and Defendant Shams.

Medically Unnecessary and Unreasonable "Follow Up" Procedures

67. Under the Government's reimbursement rules, the role of a vascular access center and the physicians working in them should be limited to two areas. First, sometimes, after referral by the patient's primary nephrologist, physicians working at an access center create the long term access necessary to perform hemodialysis by either inserting a catheter, surgically inserting an arteriovenous graft, or surgically creating an arteriovenous fistula. Second, after referral by a patient's primary nephrologist or dialysis facility, access centers perform fistulagrams and subsequent corrective procedures when clinically indicated in order to maintain optimal access performance and prevent critical

access dysfunction, thrombosis, or other complications. Access creation, fistulagrams, and corrective procedures are also sometimes performed in the hospital setting and in such instances patients are commonly ambulatory.

68. Because the government already pays for access monitoring by both the nephrologist and the dialysis facility, access centers (and the physicians employed there) have no role in monitoring a patient's access or deciding if or when additional fistulagrams and corrective procedures based upon the fistulagram findings are necessary. In other words, corrective procedures are only to be performed based upon fistulagrams initiated by referral from the patient's primary or treating neohrologist. Thus, upon receiving a referral by the dialysis facility or the treating nephrologist, access centers should perform the fistulagram requested by the nephrologist and any corrective action as indicated by the clinical history and information revealed by the fistuagram, and then refer the patient back to the dialysis facility for dialysis and for further ongoing monitoring of the access by the nephrologist and/or dialysis unit staff.

69. Moreover, because the ESRD beneficiary undergoes dialysis at least three times a week, there is an objective evaluation of the access center's treatment that is usually performed within 1-3 days after the access center has rendered their service. As such, it is the primary nephrologist and dialysis unit, and not the access center, that determines and confirms if the corrective procedure was successful. Furthermore, the access center does not have the right to decide whether follow-up diagnostic angiography or other surveillance or corrective interventions should be performed pending subsequent, ongoing evaluation by the primary nephrologist and the patient's dialysis unit staff.

70. Access centers also have no need to monitor patients after completing the procedure requested by the dialysis facility or nephrologist, or to schedule a follow-up office visit or examination to do so. Indeed, because access centers stand to gain additional compensation by keeping patients under their care, there is a clear overutilization risk associated with access centers directing patient treatment.

71. Rather than providing services in the most efficient method possible, many access centers, including those associated with Dr. McGuckin and Dr. Shams, maintained a corporate-wide practice of "holding on to" or “capturing” patients for ongoing monitoring and treatment. Such monitoring therefore was duplicative and medically unnecessary.

72. Specifically, providers, such as Dr. McGuckin and Dr. Shams, engaged in this practice by creating corporate-wide policies of instructing ESRD patients to return for "follow-up" visits. This is called “self-referral” because, instead of the primary nephrologist or a dialysis facility referring the patient for a fistulagram-based evaluation and possible corrective procedures to be performed as indicated upon the their arteriovenous vascular access system, the vascular access center would refer and reschedule patients it had worked on for additional visits irrespective of the outcomes of subsequent dialysis and evaluations by the treating nephrologist. This is illegal under the Medicare and Medicaid programs.

73. During these follow-up visits defendants would provide a number of medically unnecessary services such as evaluation of an ESRD patient's access site with ultrasound and/or angiography. Defendants performed these procedures without the

routine input or recommendation of the patient's dialysis center or treating nephrologist, and for the purpose of maximizing profit.

74. Dr. McGuckin's fraudulent practices are set forth below because they sensitized Dr. Levine to become aware of similar fraudulent practices engaged in by Dr. Shams and knowingly condoned by the Matalon defendants, as set forth below. Moreover, Dr. McGuckin's practices informed Dr. Levine's understanding of what Dr. Shams meant when he stated to Dr. Levine in relation to the case of Dr. Levine's patient RG (see below) that "everyone does it."

75. Dr. McGuckin instructed Dr. Levine that each time a vascular access patient visited a VAC clinic that they should be "squirted with dye," a phrase which meant that every patient, at a minimum, should undergo a fistulagram regardless of whether or not the primary nephrologist, dialysis staff, or Dr. Levine believed it was clinically necessary, or whether or not the patient's presentation to the access center was initiated by a primary or treating nephrologist because of a valid clinical reason for referral.

76. Dr. McGuckin instructed Dr. Levine to "bang 'em all" which meant that whenever a vascular access patient was on the operating table, all of the patient's stenoses detected by fistulagram were to be dilated by angioplasties or stents, regardless of whether or not Dr. Levine believed it was clinically necessary and whether or not the patient's presentation was initiated secondary to "self-referral" or a valid clinical concern detected by the patient's nephrologist. In other words, it was understood any and all stenoses were to be angioplastied, and possibly also stented, regardless of how well the

access was actually functioning, and whether or not the stenosis seen by x-ray was clinically relevant.

77. Dr. McGuckin further required that, at the very least, his patients be ordered to return for a subsequent follow-up angioplasty in order to "secure" their newly placed stents. There is no clinical indication for this practice, and it was only performed to increase reimbursement.

78. In addition, Dr. Levine observed Dr. McGuckin ordering his nursing staff to bill for multiple angioplasties within individual anatomic vessel segments in violation of CMS rules and accepted standards for reasonable billing practices.

79. Additionally, Dr. Levine observed that Dr. McGuckin had implicit standing orders requiring that all patients who had received a successful percutaneous thrombectomies return two weeks after the procedure for a surveillance fistualagram. These fistualgrams were entirely unnecessary, particularly since the dialysis centers would be in a position to monitor the success of the procedure during the subsequent dialysis sessions immediately following the thrombectomy procedure. Furthermore, Dr. Levine observed all patients who underwent procedures in Dr. McGuckin's New Jersey access centers were routinely scheduled for follow-up visits at three months, if not earlier. As described above, it was understood these patients were to undergo fistulagram, at a minimum, when they presented for their next scheduled appointments.

80. Dr. Levine observed that the interventional physicians (be they interventional radiologists or some other sub-specialty) employed by any given access center followed a uniform practice as far as to whether they followed the Medicare and Medicaid rules, or, instead, engaged in unnecessary follow-up visits and procedures. For

example, Dr. Levine observed while working in Milwaukee and elsewhere throughout his medical career that he himself followed the rules, and only referred his hemodialysis patients for fistulagrams based on his examination and the clinical records he maintained for the patient. Dr. Levine also observed that other doctors working in the same practice in Milwaukee similarly followed the rules.

81. Moreover, when practicing as an interventional nephrologist in Milwaukee, he would exclusively perform fistulagrams upon patients who were referred by other physicians, and only when they were referred for a well-defined and accepted clinical indication. While practicing in Milwaukee, Dr. Levine was never aware of a fistulagram referral that was initiated by a doctor who performed the fistulagram, or by a hospital or access center where the fistulagram was to be performed. Furthermore, he was never aware of a fistulagram being scheduled for the purpose of routine access surveillance.

82. In contrast, Dr. Levine observed that interventionists at Dr. McGuckin's access centers did the opposite by performing unnecessary fistulagrams and procedures. Dr. McGuckin terminated Dr. Levine from employment because he refused to follow this practice.

83. In other words, a given access center would exhibit a "culture," either of legality or illegality. To continue to be employed at a particular access center, a physician would be required to adhere to the "culture" of that access center.

84. Dr. Levine went on to observe that Dr. Shams and Beth Israel Medical Center's vascular access center followed the same culture of performing medically unnecessary procedures, as did Dr. McGuckin and his VACs/PAC.

The False and Fraudulent Practice of Ordering Automatic "Self-Referrals" By Dr. Shams and other Beth Israel Radiologists

85. Dr. Levine became aware that Dr. Shams and other Beth Israel radiologists engaged in a practice of "self-referral" identical to that of Dr. McGuckin and his clinics. Multiple times Dr. Levine was informed by patients he cared for while employed by Dr. Matalon that the patients were to return for follow-up appointments for access evaluations even though neither Dr. Levine, nor any of the other healthcare professionals in the dialysis units, initiated the referrals.

86. One example was Patient RG, who, about the summer of 2009, experienced access thrombosis and was referred to Beth Israel for access declotting, also known as a percutaneous thrombectomy. Often when an artierovenous access experiences thrombosis, the underlying problem is a flow-limiting narrowing(s) in the access system, which requires angioplasty in order for the thrombectomy to be successful and have a durable outcome. In RG's case, the procedure was performed successfully and the access appeared by all available measures to be functioning adequately, and therefore at the time Dr. Levine saw the patient there was no reason for a repeat fistulagram. However, RG was scheduled for a follow-up visit to the Beth Israel Union Square Radiology Center. Dr. Levine, after evaluation of the access, recommended that RG did not need to return for the two week follow-up appointment that the Union Square Center had arranged following the successful thrombectomy.

87. In the case of RG, Dr. Levine called and spoke to Dr. Shams to see if there was some particular reason the patient needed to be seen so soon after the successful declotting, which was entirely contrary to Dr. Levine's experience when performing

access procedures, and in this case as it applies to a successful percutaneous thrombectomy. Additionally, the mere fact Dr. Shams and the Beth Israel Union Square Center took it upon themselves to schedule RG for a follow-up fistulagram was contrary to what he understood to be within the boundaries of good medical practice and Medicare regulations. Dr. Shams admitted to Dr. Levine that it was their routine practice to schedule patients for a two week follow-up following angioplasty associated with a percutaneous thrombectomy, and that "everyone did it" including American Access Care.

88. Dr. Shams further claimed to Dr. Levine that they found a high incidence of clinically significant restenosis two weeks post-declotting. Because this was contrary to the published medical literature, Dr. Levine suggested Dr. Shams publish on his findings. As far as Dr. Levine is aware, Dr. Shams did not do so. Dr. Shams further told Dr. Levine that if Dr. Levine did not believe a follow-up visit by RG to the Union Square access center was necessary, RG did not have to return, thus revealing that Dr. Shams' claim about frequent two-week restenosis was a pretext for Dr. Shams' and Union Square's scheduling of a medically unnecessary follow-up visit. Dr. Levine recommended that RG not return unless and until there were clinical indications that RG was experiencing further complications with his/her access.

89. Dr. Shams' implication that he dealt with Patient RG (and his other patients) in the same way as American Access Care is telling. In June 2015, the Department of Justice (DOJ) settled an FCA qui tam suit against American Access Care Miami LLC alleging that it engaged in the very same unnecessary and illegal practices as described herein (brought by a different relator).

90. Further, the then medical director of American Access Care, Dr. Greg Miller, had related to Dr. Levine at a conference in San Francisco in about October 2010 that he routinely performs angioplasties and inserts stents into cephalic vein arch stenoses. (This is a frequent site of difficult to treat stenosis formation but there is no evidence-based justification to routinely stent lesions at this site, and in fact there is concern such an intervention can be detrimental because it can lead to damage of the adjacent subclavian vein rendering the ipsilateral extremity unusable for future access creation.) Moreover, Dr. Levine saw a procedure report from American Access Care on patient KF who underwent a declot procedure in September, 2011. Even though it appeared the procedure was successful, American Access Care scheduled the patient for a return visit in two weeks.

91. Thus, Dr. Shams' statement to justify his routine scheduling of Patient RG for follow-up medical appointments because "everyone did it" including American Access Care bolstered Dr. Levine's conclusion that Dr. Shams engaged in these unnecessary and illegal practices as a matter of course.

92. Similarly to the situation with Patient RG, in about June 2011, Dr. Levine treated Patient JO. JO experienced access thrombosis, and also was referred to Beth Israel for declotting. This procedure was successful. Yet, Dr. Levine learned that JO also had been scheduled for a two week follow-up visit to Beth Israel's access clinic. Dr. Levine recommended that JO not return unless and until there were clinical indications that JO was experiencing further complications with his/her access.

93. Dr. Levine was the primary nephrologist for Patient MH. MH was undergoing dialysis at the Beth Israel Dialysis Unit at Irving Place in Manhattan. MH had

undergone an access procedure in February 2011 (prior to Dr. Levine assuming the role as his/her primary nephrologist) because, at that time, MH's access flow was depressed. It was restored to its baseline following the procedure.

94. Following that successful procedure, MH underwent multiple repeat procedures at Beth Israel Union Square Center, even though his/her access was performing well based on overt clinical parameters as well as having stable intra-access blood flows, the latter being the most accurate and objective measure of access function, according to many experts in the field. MH explained to Dr. Levine that she/he went repeatedly to Beth Israel because they told him/her to do so, and because she/he was afraid if she/he did not go, something bad would happen to him/her. Dr. Levine had not initiated these referrals and Dr. Levine was not aware of any other medical professional initiating the referrals of MH for repeat visits to Beth Israel. That is so, notwithstanding a report indicating that a Dr. Steven Haveson was the referring surgeon. Dr. Levine, based on his course of treatment of MH, believed Dr. Haveson was not treating MH at the time the record said the latter had referred MH to Beth Israel. Furthermore, Dr. Levine is aware that MH has had significant allergic reactions to the administered x-ray contrast fluid on occasions when she received repeat angiograms at Beth Israel.

Dr. Sham's and Beth Israel's False and Fraudulent Medicare and Medicaid Claims

95. On information and belief, Dr. Shams and other interventionists working for Beth Israel billed for these unnecessary visits and procedures using Forms 1450 and/or Forms 1500. Dr. Levine did not have access to the billing department or personnel at Dr. Sham's and Beth Israel's vascular access facilities. Consequently, specific knowledge regarding these false claims is peculiarly within the knowledge of Defendants.

Dr. Levine's knows from personal observation and experience that it is routine practice for interventionists who participate in the Medicare and Medicaid programs, as Dr. Shams and Beth Israel did, to bill these programs for their services.

96. The fact that Dr. Shams submitted billings for these procedures to Medicare and Medicaid is confirmed by data maintained by CMS.

97. According to this CMS data, for example, in 2012, Dr. Shams submitted $4,806,017 in billings to Medicare; Medicare allowed $374,755 worth of these claims; and Medicare paid Dr. Shams $298,926 for these claims.

98. In 2013, Dr. Shams submitted billings of $5,220,723 to Medicare; of which $351,605 was allowed; and $276,117 was paid.

99. In 2014, Dr. Shams submitted billings of $4,342,954 to Medicare; of which $271,979 was allowed; and $212,838 was paid.

100. Dr. Shams almost doubled his Medicare billings in 2015. In that year, Dr. Shams submitted billings of $9,490,786 to Medicare; of which $2,710,386 was allowed; and $2,124,713 was paid. Thus, from 2014 to 2015, the revenues Dr. Shams received via the Medicare program multiplied by almost 10 times.

101. Dr. Shams' pattern of increasing billings and increasing revenues from Medicare continued over the next two years. In 2016, Dr. Shams billed $14,242,155; was allowed $4,050,407; and was paid $3,175,518.

102. In 2017, Dr. Shams billed $12,495,154; was allowed $4,070,710; and was paid $3,188,749.

103. Thus, the monies Dr. Shams received from his Medicare claims increased from $298,926 in 2012 to $3,188,749 in 2017, an almost eleven-fold increase; yet, the

number of Medicare beneficiaries Dr. Shams treated only increased from 371 in 2012 to 427 in 2017, which was not even a doubling.

Circumstantial Evidence of the False and Fraudulent Nature of Dr. Shams' Claims for Angioplasties

104. Indicative of the lack of medical necessity of the procedures Dr. Shams performed and his practice of self-referral is the quantity of certain procedures Dr. Shams carried out per patient per year. An example is HCPCT Code 35476, "Balloon dilation of narrowed or blocked vein." This is an angioplasty of an alleged narrowing located in the access vessel (fistula or graft) and or in the venous vasculature draining the access vessel. In 2012, Dr. Shams performed 415 such procedures on 121 different patients, which is an average of 3.4 venous angioplasties per patient in that year. This placed him as 17th highest per patient per year in the United States out of 3,239 physicians executing this procedure. This means that, on average, Dr. Shams performed a follow-up venous angioplasty on each of his patients every 3.5 months.

105. During 2013, Dr. Shams carried out this procedure 470 times on 127 patients, or, in other words an average of 3.7 times per patient, or once every 3.2 months. His ranking that year out of all 3,306 physicians in the United States performing this procedure that year was 11th with respect to the number of venous angioplasties per patient.

106. In 2014, he performed 346 such services on 96 patients for an average per-patient frequency of 3.6. This placed him 15th out of 3,189 physicians executing this procedure with respect to the number of venous angioplasties per patient.

107. In 2015, Dr. Shams performed 507 venous angioplasties per 154 patients, which is an average rate of 3.3 such procedures per patient. His ranking in the United

States was 15th out of 3,161 physicians performing this procedure with respect to the number of venous angioplasties per patient.

108. In 2016, Dr. Shams performed 774 venous angioplasties on 193 patients, or an average of 4 procedures per patient per year, once every 3 months, which placed him 7th out of 3,201 doctors performing this procedure in the nation with respect to the number of venous angioplasties per patient!

109. The data supports a reasonable inference that Dr. Shams billed the Government during these years for unnecessary venous angioplasties.

110. In addition, during 2012-2017, Dr. Shams charged the Government under HCPCS Codes 99214, "Established patient office or other outpatient, visit typically 25 minutes"; 99204, "New patient office or other outpatient visit, typically 45 minutes"; and other Codes reflecting routine office visits. Based on his personal experience performing interventional services, Dr. Levine believes that the Code for the interventional procedure itself is intended by Medicare and Medicaid to compensate the interventionist for the pre-operative and post-operative services he or she delivers in conjunction with the procedure itself. Therefore, there is no medical reason the interventionist would charge separately for an office visit, unlike in the case of a treating physician who sees a patient in the outpatient office setting for a medical problem and not immediately prior to performing an invasive procedure. Regarding non-invasive examination and evaluation of the dialysis access immediately prior to performing a fistulagram and possible balloon angioplasty, this would have been performed by the primary or treating nephrologist resulting in the referral in the first place. Billing for such a service is clearly duplicative.

In other words, charges by Dr. Shams for office visits would be medically unnecessary and therefore illegal under Medicare and Medicaid.

111. Dr. Levine will conduct discovery to obtain additional evidentiary support for the lack of medical necessity or justification of Dr. Shams' procedures on other patients besides RG, JO, and MH.

Causal Role of the Drs. Matalon in Dr. Sham's FCA Violations, and Submission by the Matalons of False Claims for Capitation Payments

112. As mentioned above, Defendants Robert Matalon and his sons Daniel and Albert are members of Nephrology Associates of Manhattan. In addition they own, and/or manage a series of kidney dialysis facilities throughout Manhattan.

113. The Matalon Defendants regularly referred their patients, and the patients of other treating nephrologists receiving dialysis at their facilities, to Dr. Shams' vascular access center, knowing that he engaged in the practice of self-referrals, and therefore knowing that he was generating unnecessary and unreasonable claims to the Medicare and Medicaid Programs. By so doing, the Matalon Defendants caused the false and fraudulent claims submitted by Dr. Shams and the Beth Israel vascular access centers.

114. The following observations by Dr. Levine, and other information known to Dr. Levine, supports the conclusion that the Matalon Defendants knew (that is, had actual knowledge, acted in deliberate ignorance, or acted in reckless disregard) of the improper self-referral practices carried out by Dr. Shams and the Beth Israel vascular access centers, and therefore of the false and fraudulent nature of their claims.

115. Dr. Levine observed that Dr. Robert Matalon went along and collaborated with the vascular access centers to which he referred patients, including Dr. Shams and

Beth Israel, by allowing, or at least not stopping, the patients from going for appointments to these centers on a regular basis to have their accesses evaluated without proper referrals made by him or othere staff for specific clinical indications. Furthermore, Dr. Levine observed when Dr. Matalon learned some patients receiving dialysis in his units were going for access procedures to doctors other than Dr. Shams, he instructed the Chinatown Dialysis Unit support staff whose responsibility it was to schedule such appointments and arrange the necessary van transport (to be discussed in detail below) to intensify their efforts to direct as many patients as possible to Dr. Shams and the Beth Israel Union Square Center. It was virtually inevitable that the Drs. Matalon would learn that their patients were undergoing unnecessary procedures in view of the fact that patients invariably provide feedback to their treating physicians regarding the examinations and procedures specialists perform on the patients as a result of referrals by the primary to the specialists. Additionally, there is usually physical evidence of the procedure, such as a suture or bandage that is readily observable to the treating nephrologist. Furthermore, it is standard medical procedure for a specialist who performs a procedure on a patient to send "procedure notes" to the primary physician, which are then added to the patient's chart.

116. Specifically, the vascular access centers performing excessive and unnecessary angiograms, angioplasties, and other interventional procedures would have sent notes documenting the performed procedures to the Drs. Matalon for patients under their care, and for patients sent from their dialysis units to the access centers. Those procedures would have been added to these patients' charts. Those charts would routinely and regularly have been reviewed by the Drs. Matalon, and the staff of their dialysis

units, in the normal course of further treating the patients, and that review would have informed the Matalons of the practice of the vascular access centers, including those of Dr. Shams and Beth Israel, of engaging in self-referrals.

117. Moreover, the Matalons' patients and those being treated in their dialysis units would routinely and regularly have discussed the fact that they were being self-referred by the access center.

118. Three examples of patients treated by Dr. Levine, RG, JO, and MH, who discussed their self-referral experiences with Dr. Levine are set forth above. Dr. Levine treated RG and JO while they were patients of the Drs. Matalon or of the Matalon-owned and controlled dialysis facilities.

119. Another example is the Matalons' Patient CB, who was a medical professional. CB told Dr. Levine that he/she was undergoing angiograms and angioplasties about every three months. Dr. Levine asked CB why this was the case. CB answered he/she could not provide a specific indication for these repeated procedures, and acknowledged it might be an example of a medical "New York hustle." He/she also stated he/she was dealing with so many other personal and medical issues that he/she didn't even want to think that perhaps he/she was allowing himself/herself to undergo medically unnecessary procedures.

120. Many dialysis patients are poor and lack transportation. If they are too ill to travel by public transportation, the Government reimburses the cost of a van to transport patients to medical providers. Many of the patient's in the Matalon dialysis units legitimately required such transportation support to travel to and from the dialysis units. In addition, other medical appointments the patients in Dr. Matalon's units

required, including appointments with access centers, were arranged by the support staff employed by Dr. Matalon. When scheduling the appointment, including at access centers, the staff would also arrange the necessary van transport. By ordering and/or authorizing his staff to schedule access related appointments with specific providers such as Dr. Shams, and because the van-dependent patients could only travel to the destinations that the staff arranged, Dr. Robert Matalon, with the full knowledge of Dr. Daniel and Dr. Albert Matalon, used the Government's transportation largesse to "steer" patients from his dialysis facilities to the access centers they knew were engaged in self-referrals. This system of arranging transport to the access centers would have also placed the Matalons on notice of the excessive frequency with which their patients were returning unnecessarily to the access centers.

121. Dr. Levine observed Dr. Robert Matalon boasting that all decisions for referral to vascular access centers must meet a “What’s in it for me?” test.

122. At some point when Dr. Levine was working with Dr. Robert Matalon, the latter commented to Dr. Levine that he was considering opening his own access center. Dr. Levine pointed out to Dr. Matalon that, in estimating the profitability of an access center, he would have to discount the portion of revenues that many such centers received from illegal self-referrals; in other words, he could not rely on the revenues of such facilities as Dr. McGuckin’s to predict the potential profitability of any access center he (Dr. Matalon) opened because of the improper activities engaged in by the former. Dr. Matalon responded back to Dr. Levine’s advice with words to the effect of “a number of them [vascular access facilities] are shady.” This conversation shows that Dr. Matalon

was on notice of the rampant nature of the self-referral practices by many vascular access centers, including those of Dr. Shams and Beth Israel.

123. Yet, the Drs. Matalon continued to feed a steady stream of patients to these fraudulent vascular access centers performing unnecessary procedures and non-covered vascular access monitoring and surveillance, and did so over many years, thereby knowingly causing the false and fraudulent claims submitted to the Government by the latter.

124. As discussed above, dialysis facilities and treating nephrologists are required by the government's reimbursement rules to provide for the assessment and management of a number of areas unique to the ESRD patient, including monitoring the efficacy of a patient's vascular access. In return for these services, both the treating nephrologist and the dialysis facility receive up to four monthly capitated payments in the case of the former, and payment per treatment in the case of the latter from the Government.

125. Rather than monitoring of their patient's access sites, the Matalons "farmed out" the management and observation of patients' access to the access clinics operated by Dr. Shams and Beth Israel. If they had been performing access surveillance as required by Medicare and Medicaid regulations, they would not have permitted their patients to submit to fistulagrams and other procedures at the access centers without the proper clinical indications. In knowingly so doing, they vitiated the medical necessity of their own claims for capitated payments, and therefore rendered those claims false within the meaning of the FCA.

126. Dr. Levine estimates, based on CMS data, that, during the years 2012 through 2017, Dr. Albert and Dr. Daniel Matalon were paid several hundred thousand dollars in capitation payments.

127. Dr. Levine will conduct discovery to obtain additional evidentiary support for the lack of medical necessity or justification for other of Dr. Shams' procedures on other patients of the Matalons besides RG, JO, MH, and CB.

ESTIMATE OF THE MINIMUM QUANTUM OF DAMAGES ARISING FROM DR. SHAMS' FALSE CLAIMS

128. On information and belief, at least 27% of the angioplasties Dr. Shams performed in 2012 were medically unnecessary. This percentage is based on an estimate by a medical expert in another matter involving similar fraud allegations that was settled by the Department of Justice.[3] Thus, assuming that 112 of Dr. Sham's angioplasties in 2012 were unnecessary this would have resulted in FCA damages of 112 times $224, which was the average reimbursement Medicare made to Dr. Shams for this procedure in 2012, or total single damages based on this procedure alone of at least $25,088.

129. The damages for 2012 (and the other years below) are considerably higher than this figure, however. Besides billing HCPCT Code 35476 for the angioplasty procedure, Dr. Shams would have billed other HCPCT codes depending on the particular unnecessary self-referred procedure being performed, such as HCPCT Code 36902,

[3] *See* Docket Entry 53, "Omnibus Order Granting United States' Motion To Strike Relator's Motion In Opposition To Settlement Agreement (D.E. 47), Striking Relator's Motion In Opposition To Settlement Agreement (D.E. 41), Granting Joint Motion Of United States And Defendant To Dismiss Settled Claims (D.E. 46), And Closing Case," dated June 29, 2015, in United States of America, ex rel. Dennis A. Souza v. American Access Care Miami, LLC, Case No. 1:11-cv-22686-JAL (S.D. Fla.) at 2, available via PACER.

"Insertion of needle and/or catheter into dialysis circuit and balloon dilation of dialysis segment, with imaging including radiological supervision and interpretation," and HCPCT Code 36903, "Insertion of needle and/or catheter into dialysis circuit and insertion of stent in dialysis segment, with imaging including radiological supervision and interpretation."

130. On information and belief, using the same assumption, at least 27% of the angioplasties Dr. Shams performed in 2013 were medically unnecessary. Hence, 127 of Dr. Sham's angioplasties in 2013 were unnecessary resulting in FCA damages of 127 times $176, which was the average reimbursement Medicare made to Dr. Shams for this procedure in 2013, or total single damages of at least $22,352. Again, additional damages would arise from Dr. Shams' performance of other unnecessary self-referred procedures in 2013.

131. On information and belief, using the same assumption, at least 27% of the angioplasties Dr. Shams performed in 2014 were medically unnecessary. Hence, 93 of Dr. Sham's angioplasties in 2014 were unnecessary resulting in FCA damages of 93 times $196, which was the average reimbursement Medicare made to Dr. Shams for this procedure in 2014, or total single damages of at least $18,228, plus damages attributable to other unnecessary self-referred procedures in this year.

132. On information and belief, using the same assumption, at least 27% of the angioplasties Dr. Shams performed in 2015 were medically unnecessary. Hence, 137 of Dr. Sham's angioplasties in 2015 were unnecessary resulting in FCA damages of 137 times $1,019, which was the average reimbursement Medicare made to Dr. Shams for

this procedure in 2015, or total single damages of at least $139,603, plus damages attributable to other unnecessary self-referred procedures in this year.

133. On information and belief, at least 27% of the 774 angioplasties Dr. Shams performed in 2016 were medically unnecessary. Thus, 209 of Dr. Sham's angioplasties in 2016 were unnecessary resulting in FCA damages of 209 times $1,051, or total single damages of at least $219,659, plus damages attributable to other unnecessary self-referred procedures in this year.

134. Dr. Levine has not yet estimated damages for 2017, or for the years prior to 2012 going back to June 30, 2006, all of which prior years' false claims are within the 6-year FCA statute of limitations inasmuch as the statute of limitations relates back to June 29, 2012, when Dr. Levine initially filed this action.

135. At the very least, Dr. Levine estimates that the total single damages from the false and fraudulent claims submitted by Dr. Shams, and caused to be submitted by the Drs. Matalon, are $424,930, which damages are subject to trebling to $1,274,790. Defendants are also subject to the imposition of civil penalties pursuant to the FCA.

136. Dr. Levine has not yet estimated the damages arising from the Matalons' submission of false claims for capitated payments.

137. This is an estimate only, with the actual amount of damages to be determined by the jury at trial.

COUNT ONE
(All Defendants)

(31 U.S.C. § 3729 (a) (1) (Federal False Claims Act)
New York False Claims Act - State Fin. Law § 189(1)(a),
(Knowingly Presenting a False or Fraudulent Claim)

138. Dr. Levine incorporates the foregoing paragraphs as if fully set forth herein.

139. By virtue of the acts described above, Defendants knowingly presented, or caused to be presented, to officers, employees, or agents of the United States Government false or fraudulent claims for payment or approval.

140. Defendants knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of said claims, or acted in reckless disregard of whether said claims were true or false. These claims were, therefore, false or fraudulent claims submitted for payment or approval to the United States in violation of 31 U.S.C. Section 3729(a) (1) and the New York False Claims Act State Fin. Law § 189(1)(a).

141. Plaintiff, the United States, unaware of the foregoing circumstances and conduct of Defendants, and in reliance on the accuracy of said false or fraudulent claims, made payments to Defendants, which resulted in the United States being damaged in an amount to be established at trial or upon motion for summary judgment, but which are estimated to be at least $424,930, which damages are subject to trebling to $1,274,790. Defendants are also subject to the imposition of civil penalties pursuant to the FCA.

COUNT TWO
(All Defendants)

(31 U.S.C. § 3729 (a) (2) Federal False Claims Act
New York False Claims Act - State Fin. Law § 189(1)(b);
(Knowingly Making, Using, or Causing to be Made or Used, a
False Record or Statement)

142. Plaintiff-Relator incorporates by reference the preceding paragraphs as if fully set forth herein.

143. By virtue of the acts described above, Defendants made, used, or caused to be made or used, false records and statements material to false and fraudulent claims.

144. The United States and the State of New York, unaware of the foregoing circumstances and conduct of Defendants, and unaware of the falsity of the records and or statements made, used, or caused to be made or used by Defendants, and in reliance on the accuracy thereof, paid the false or fraudulent claims submitted it, which resulted in the United States being damaged in an amount to be established at trial or upon motion for summary judgment, but which are estimated to be at least $424,930, which damages are subject to trebling to $1,274,790. Defendants are also subject to the imposition of civil penalties pursuant to the FCA.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Relator, on behalf of himself, the United States of America, and the State of New York, demand judgment against Defendants as follows:

A. All Counts:

(a) Trebling the amount of damages sustained by the United States, in an amount to be established at trial equal to the amount of false claims submitted by Defendants;

(b) Assessing a civil penalty of $10,000 for each false or fraudulent claim that Defendants made or caused to be made to the government;

(c) Imposing all other necessary and proper relief, including the costs of this action.

In addition, Plaintiff-Relators on their behalf further demand:

(a) That, in the event that the United States of America or the State of New York proceed with this action or otherwise settles these claims, the Court award to Plaintiff-Relators, an amount of the proceeds of this action or settlement of these claims of not less than 15% and as much as 25%, together with an amount of reasonable expenses incurred by Plaintiff-Relators, plus reasonable attorneys' fees and all costs and expenses incurred by the Plaintiff-Relators in bringing this action.

(b) That in the event that the United States of America does not proceed with this action, the Court award to Plaintiff-Relators, an amount of the proceeds of this action or settlement of claims of not less than 25% and as much as 30%, together with an amount of reasonable expenses incurred by Plaintiff-Relators, plus reasonable attorneys' fees and all costs and expenses incurred by the Plaintiff-Relators in bringing this action.

(c) Such other and further relief that this Court deems just and proper.

Jury Demand

Pursuant to Fed. R. Civ. P. 38, Plaintiff-Relator demands trial by jury.

Dated: August 5, 2019

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